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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,378	10/07/2003	David Carlson	39147-0016	4289
26633 7590 01/09/2007 HELLER EHRMAN LLP 1717 RHODE ISLAND AVE, NW WASHINGTON, DC 20036-3001			EXAMINER CHUNDURU, SURYAPRABHA	
			ART UNIT	PAPER NUMBER
			1637	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/09/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/679,378	Applicant(s) CARLSON ET AL.	
	Examiner Suryaprabha Chunduru	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 04, 2006 has been entered.

Status of the Application

2. The action is in response to the RCE filed on December 04, 2006. Claims 1-12, 14-15 are pending. Claims 13, and 16-20 are cancelled. All arguments have been thoroughly reviewed and deemed persuasive for the reasons that follow.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12, 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huhne et al. (Int J Legal Med., Vol. 112, pp. 172-175, 1999) in view of Swason et al. (USPN. . 4, 548,608) and Shi et al. (J Histochem and Cytochem., Vol. 50(8), pp. 1005-1011, August, 2002).

Huhne et al. teach a method of claim 1, 14, for extracting DNA from a biological sample, wherein the biological sample is human hair (hair shaft) containing no hair root (see page 172, col. 2, paragraph 1-3 under Materials and Methods section), said method comprising contacting the sample with a basic solution (pH 9.0) comprising an effective concentration of a chelating agent, an effective concentration of a stabilizing agent, and an effective concentration of a buffering agent (see page 172, col. 2, paragraph 3 under Materials and Methods section). Huhne et al. also teach no grinding of hair before DNA extraction (see page 172, col. 2, paragraph 1-3 under Materials and Methods section).

However, Huhne et al. did not specifically teach highly basic solution comprising alkali metal gluconate salt (sodium gluconate), alkali metal silicate and alkali metal phosphate.

Swanson et al. teach a composition for hair loosening process, said composition comprises sodium gluconate as chelating agents wherein said composition comprises predetermined concentrations of sodium gluconate, sodium silicate and sodium phosphate (see col. 2, line 38-52); Swanson et al. also teach that the sodium phosphate due to its buffering ability maintains the high pH (pH-13) thus extending an alkaline contact time with disulfide bonds of protein in the biological sample and sodium gluconate acts as a chelating agent (see col. 3, line 14-39); said composition comprising sodium gluconate facilitates o achieve loosening of hair (see col. 3, line 14-64). Swason et al. also teach that the composition comprises a high level

of alkalinity and hydrogen ion concentration with a pH values between 12 to 13.5 (see col. 5, line 11-21).

Further Shi et al. teach a method for DNA extraction from archival tissue samples wherein Shi et al. teach that the method comprises analyzing the influence of pH ranging from (pH 2 to 12.0) and heating on the efficiency of DNA extraction (see page 1008, table 2), wherein Shi et al. teach that a strongly alkaline solution facilitates denaturing and hydrolyzing proteins, rupturing the cell membranes and improves DNA extraction (see page 1011, col. 1, paragraph 1).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method for extracting DNA as taught by Huhne et al. with a step of including highly basic alkaline solution comprising alkali metal gluconate salt, sodium gluconate as chelating agent, sodium phosphate buffering agent as taught by Swanson et al. for the purpose of increasing alkalinity or pH of the solution to promote alkaline lysis because Swanson et al. explicitly taught that sodium gluconate acts as a chelating agent or sequestering agent and facilitates hair loosening process and sodium phosphate due to its buffering ability stabilizes the high pH (pH-13) extends an alkaline contact time with disulfide bonds in hair protein (see col. 3, line 14-39, line 29-58) and said composition is formulated to achieve loosening of the hair protein by attacking active disulfide bonds in cystine hair protein in alkaline solution (see col. 3, line 14-68). Shi et al. further supports the improvement of DNA extraction with a strongly alkaline solution, and explicitly taught that the proteins in the biological cell membranes are denatured and hydrolyzed by the use of strong alkali solution and improves the DNA extraction (see page 1011, col. 1, paragraph 1). An ordinary artisan would have a reasonable expectation of success that modifying the method of DNA extraction as taught by

Huhne et al. with the inclusion of highly basic solution comprising sodium gluconate, sodium silicate and sodium phosphate as taught by Swanson et al. and the teaching of Shi et al. would result in a highly basic (alkaline) solution that would aid in alkaline lysis of DNA in a hair sample and such modification of the method is considered obvious over the cited prior art. Further as noted in *In re Aller*, 105 USPQ 233 at 235, More particularly, where the general conditions of a claim are disclosed in the prior art (Swason et al.), it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the selection of concentrations of chelating, stabilizing and buffering agents performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Response to arguments:

4. With regard to the arguments on the claim interpretation regarding the term highly basic solution, Applicants' arguments are fully considered and found persuasive.
5. With regard to the rejection under 35 USC 102(e) as anticipated by Lai et al., Applicants' arguments are fully considered and the rejection is withdrawn in view of the arguments. The rejection is withdrawn herein and new grounds of rejections are applied to address the issue of highly basic solution and hair with no hair root.
6. With regard to the rejection under 35 USC 103(a) as being unpatentable over Lai et al. in view of Swason Applicants' arguments and amendment are fully considered and the rejection is withdrawn in view of the arguments and new grounds of rejections.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Primary Examiner
Art Unit 1637

Prabha Chunduru
SURYAPRABHA CHUNDURU
PRIMARY EXAMINER 1/5/07